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10/537,787

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EXAMINER

SALMON, KATHERINE D

ART UNIT

PAPER NUMBER

1634

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/29/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/537,787

Applicant(s)

CLAEYS ET AL.

Examiner

Katherine Salmon

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/12/05, 6/06/05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Claims 1-7 and 15-16 and the SEQ ID No. 1, 2, 7, and 9 in the reply filed on is acknowledged.

The reply asserts that based on the assertion that the newly amended claims make a contribution over the prior art (p. 6 3<sup>rd</sup> paragraph). The reply asserts that the newly amended Claim 3 and the new claim 16 are not reflective of Gurtler et al. (p. 6 last paragraph). The reply asserts that with regard to the requirement for a selection of probes that all the probes share a common property and activity, the detection of *Staphylococcus* species, therefore should not be separated (p. 7 last paragraph and p. 8).

These arguments have been fully considered but have not been found persuasive.

Claim 3 is drawn to "a fragment of at least 20 nucleotides of SEQ ID NO. 1". Claim 16 is drawn to a probe, which specifically hybridizes to SEQ ID No. 2 or to at least 20 contiguous fragments of SEQ ID No. 2. It is noted that SEQ ID No. 1 is the degenerative sequence of SEQ ID NO. 2. The technical feature that is shared by the claims is a fragment of at least 20 mer of SEQ ID No. 2. Gurtler, as shown in the requirement for restriction mailed 9/27/2006, comprises a sequence which is identical to the instant application SEQ ID No. 2 (and also SEQ ID No. 1) at greater than 20 contiguous nucleotides (see p. 2 of requirement for restriction).

Art Unit: 1634

Since the probes are structurally distinct, they fail to share a common structure (p. 3 of requirement for restriction). Further the probes detect a similar source, each probe detects and hybridizes to a different region of the source. As stated in the requirement for restriction, the mere fact that fragments are derived from the same source is not sufficient to meet the criteria for unity of invention (p. 3). The probes each are composed of a distinct fragment of nucleotides, which hybridize to a specific area of the genome. The search for each fragment requires a distinct search wherein there is no common property or activity for the combination of probes.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Claims 1-16 are pending. Claims 8-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. A complete reply to the final rejection must include cancellation of nonelected claims and subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

4. An action on the merits for Claims 1-7 and 15-16 is set forth below.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1634

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3-7 and 15-16 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-4, and 15-16 are indefinite. Claim 3 and 16 are drawn to "any of their homologues". It is unclear what the metes and bounds are for "any of their homologues". It is unclear which variant sequences would be encompassed by the "homologue".

Claims 3-4 are indefinite over the phrase "specifically hybridizes" in Claim 3. The phrase has not been clearly defined in the specification and there is no art recognized definition for this phrase. It is unclear as to what nucleic acids' the reagent hybridizes with and which nucleic acids' it does not hybridize with.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131

Art Unit: 1634

USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation identification of *Staphylococcus*, and the claim also recites "in particular of *S. aureus*" which is the narrower statement of the range/limitation.

Claim 5-7 and 15 are indefinite over the phrase "no more than 25 nucleotides between said probes." It is unclear if this phrase is the total length of the two probes together or the length of region between the two hybridized probes.

Claim 15 is unclear. It is unclear how "components necessary for producing said buffer" limits the claim. It is unclear which components are needed to produce the hybridization buffer.

Claim 16 is indefinite over the phrase "specifically hybridizes". The phrase has not been clearly defined in the specification and there is no art recognized definition for this phrase. It is unclear as to what nucleic acids' the reagent hybridizes with and which nucleic acids' it does not hybridize with.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-7 and 15-17 are rejected under 35 U.S.C. 112, first paragraph, as

Art Unit: 1634

failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a nucleic acid molecule consisting of SEQ ID No. 1, its complementary form, or RNA form. Claim 1 is drawn to a nucleic acid molecule consisting of SEQ ID No. 2, its complementary form, or RNA form. Claim 3 is drawn to an isolated nucleic acid that specifically hybridizes to SEQ ID No. 1, or the RNA form of SEQ ID No. 1, or to a fragment of at least 20 nucleotides or any homologue for the detection of staphylococcus. Claim 4 is drawn to an isolated nucleic molecule consisting of SEQ ID No. 17 and 19. Claim 5 is drawn to a set of two probes hybridizing to SEQ ID NO. 1 or 2 or homologues. Claim 6 is drawn to a set of two polynucleotide probes consisting of SEQ ID no. 17 and 19. Claim 7 is drawn to a composition comprising at least one nucleic acid of Claim 1 or a set of two polynucleotide probes. Claim 15 is drawn to a kit. Claim 16 is drawn to an isolated nucleic acid molecule of at most 100 nucleotides that specifically hybridized to SEQ ID No. 2.

The claims are broadly drawn to any fragment of SEQ ID No. 1 or 2, which can detect staphylococcus.

The claims are drawn to "complementary forms" of SEQ ID No. 1 or 2. "Complementary forms" does not limit the claims to "the complement" of SEQ ID No. 1 or 2, but rather any fragment of SEQ ID No. 1 or 2 that is complementary with a portion of SEQ ID No. 1 or 2. These claims as broadly written encompass sequences, which

Art Unit: 1634

are of any fragment length, and have any number of mutations or variations within the sequence.

The claims are further drawn to "at least 20 contiguous nucleotides of SEQ ID No. 1" or any homologue to detect *Staphylococcus*. Though there is functional language in the claim, the structure that is not clearly defined. The claims are drawn to any fragment of 20 mer or greater or any homologue. This broad claim language encompasses a large number of variants and mutations, which are not described in the instant specification. The specification does not define which nucleotides are critical to retain functionality and therefore there is not a clear association between structure and function.

The specification does not prove an adequate written description of the claimed genus of nucleic acids. The claims are broadly drawn to any fragments of at least 20 mer or any homologue; however, the specification only describes SEQ ID No. 1 and 2. The specification does not describe what structure is critical to retain functionality; therefore the specification has not defined the nucleic acids in terms of both structure and function.

Additionally, the claims do not set forth the number or identity of nucleotides flanking the recited nucleic acid fragments. Accordingly, the claims encompass nucleic acids which comprise the recited 20 mer fragments of SEQ ID NO: 1 but which share any overall level of sequence identity with SEQ ID NO: 1 (e.g., 80%, 60%, 10% etc). The claims thereby encompass naturally and non-naturally occurring allelic, mutant and splice variants of SEQ ID NO. 1 or 2.

The general knowledge in the art concerning homologues, mutants, allelic and splice variants does not provide any indication of how modification of the sequence of SEQ ID NO: 1 or 2 will effect the functional properties of SEQ ID NO: 1 or 2. The structure and function of one molecule does not provide guidance as to the structure and function of other molecules. Therefore, the description of one molecule (SEQ ID NO: 1 or 2) is not representative of a genus of homologues, splice, mutant and allelic variants of SEQ ID NO: 1 or 2 having unspecified functional activities different from that of SEQ ID NO: 1 or 2. A general statement in the specification of a desire to obtain gene sequences, homologues from other species, mutated species, and polymorphic sequences is not equivalent to providing a clear and complete description of specific sequences, which fall within the claimed genus of nucleic acids.

Accordingly, Applicants have not adequately disclosed the relevant identifying characteristics of a representative number of species within the claimed genus.

The specification fails to sufficiently describe the claimed invention in clear and exact terms so that a skilled artisan would recognize that the applicants were in possession of the claimed invention at the time of filing.

In analysis of the claims for compliance with written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register:

Art Unit: 1634

December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) In the instant case, the specification fails to teach the necessary common attributes or features of the genus of encompassed nucleic acids and polymorphisms in view of the species disclosed. As such, one of skill in the art would not recognize that applicant was in possession of the genus of nucleic acids and polymorphisms encompassed by the broadly claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116).

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude, "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the

Art Unit: 1634

DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The fragments or homologues of SEQ ID NO. 1 or 2 encompassed by the claims do not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly diverse. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3, 7, and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Jannes et al. (US Patent 6312903 November 6, 2001).

With regard to Claim 1, it is noted that "its complementary form" can be interpreted to broadly encompass any fragment of SEQ ID No. 1 and further SEQ ID NO. 1 with nucleotides flanking the sequence. The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *in re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *in re Zletz*,

Art Unit: 1634

893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification wherein the "its complementary form" can be interpreted broadly.

With regard to Claim 1 and 2, Jannes et al. teaches sequences for the detection of eubacterial taxa (abstract). Jannes et al. teaches a sequence (SEQ ID No. 142) which is 383 nucleotides in length. Nucleotides 174-316 of SEQ ID No. 142 are identical to SEQ ID Nos. 1 and 2 of the instant application. It is noted that SEQ ID No. 1 of the instant claims comprise symbols, which give variability to particular nucleotides at a particular position. For example nucleotide 141 is an "N" which would match at that position any sequence which has "A", "G", "C", or "T".

With regard to Claim 3, Jannes et al. teaches that SEQ ID NO. 142 detects *S. aureus* (Column 3 lines 40-43 and figure 67). Jannes et al. teaches probes that specifically hybridize to SEQ ID NO. 142 (at least 20 contiguous nucleotides of SEQ ID No. 1) such as STAU-ICG1 (Seq ID NO. 53 of Jannes et al.) (Table 1a Column 55).

With regard to Claim 7, Jannes et al. teaches a sequence (SEQ ID No. 142) which is 383 nucleotides in length. Nucleotides 174-316 of SEQ ID No. 142 are identical to SEQ ID Nos. 1 and 2 of the instant application. It is noted that SEQ ID No. 1 of the instant claims comprise symbols, which give variability to particular nucleotides at a particular position. For example nucleotide 141 is an "N" which would match at that position any sequence which has "A", "G", "C", or "T". The sequence that Jannes et al. teaches would be considered a "composition".

Art Unit: 1634

With regard to Claim 15, Jannes et al. teaches a kit for the detection of at least one microorganism (staphylococcus) comprising probes to SEQ ID No. 142 (which is encompassed by the instant Claim 1), hybridization buffer (Column 47 lines 50-65, SEQ ID No. 142, and Column 55-56).

With regard to Claim 16, Jannes et al. teaches a probe (SEQ ID No. 53). Jannes et al. teaches the probe is 30 mer in length. SEQ ID No. 53 is 100% identical to the instant SEQ ID No. 2; therefore it would hybridize to SEQ ID No. 2.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jannes et al. (US Patent 6312903 November 6, 2001).

With regard to Claims 4-6, the claims are drawn to probes, which hybridize to SEQ ID No. 1 or 2. Jannes et al. teaches sequences for the detection of eubacterial taxa (abstract). Jannes et al. teaches a sequence (SEQ ID No. 142) which is 383 nucleotides in length. Nucleotides 174-316 of SEQ ID No. 142 are identical to SEQ ID Nos. 1 and 2 of the instant application. Jannes et al. teaches designing probes based on the 16S-23S rRNA region which can detect Staphylococcus (Abstract).

Jannes et al. provides guidance to determining wherein the spacer region probes should be designed. Jannes et al. teaches from the alignment of the spacer region, regions of divergence can be defined, from which probes with desired hybridization characteristics are designed, according to guidelines known the skilled artisan (Column 4 lines 29-32).

"First, the stability of the [probe:target] nucleic acid hybrid should be chosen to be compatible with the assay conditions. This may be accomplished by avoiding long A and T rich sequences, by terminating the hybrids with G:C base pairs, and by designing the probe with an appropriate T<sub>m</sub>.

Conditions such as ionic strength and incubation temperature under which a probe will be used should also be taken into account in constructing a probe.

It is desirable to have probes which hybridize only under conditions of high stringency. Under high stringency conditions only highly complementary nucleic acid hybrids will form; hybrids without a sufficient degree of complementarity will not form.

Second, probes should be positioned so as to minimize the stability of the [probe nontarget] nucleic acid hybrid. This may be accomplished by minimizing the length of perfect complementarity to non-target organisms, avoiding GC rich

regions of homology to non-target sequences, and by positioning the probe to span as many destabilizing mismatches as possible.

The length of the target nucleic acid sequence and, accordingly, the length of the probe sequence can also be important. In some cases, there may be several sequences from a particular region, varying in location and length, which will yield probes with the desired hybridization characteristics. In other cases, one sequence may be significantly better than another which differs merely by a single base. While it is possible for nucleic acids that are not perfectly complementary to hybridize, the longest stretch of perfectly complementary base sequence will normally primarily determine hybrid stability. While oligonucleotide probes of different lengths and base composition may be used, oligonucleotide probes preferred in this invention are between about 10 to 50 bases in length and are sufficiently homologous to the target nucleic acid.

Third, regions in the target DNA or RNA which are known to form strong internal structures inhibitory to hybridization are less preferred. Likewise, probes with extensive self-complementarity should be avoided. (Column 5 lines 15-67 and Column 6 lines 1-21)."

Jannes et al. teaches that probes for detection should be used in sets comprising at least 2 probes (Column 11 lines 66-67). Jannes et al. teaches probe sets which hybridize to SEQ ID No. 142 (which comprises SEQ ID No. 1 and 2 of the instant application). Jannes et al. teaches a probe SEQ ID No. 53 that hybridizes to a region of SEQ ID No. 1 and 2 (Column 41 lines 20-50). Jannes et al. teaches other probes which hybridize to SEQ ID No. 142 (Column 41 lines 20-50). Particularly, SEQ ID no. 56 hybridizes less than 25 mer away from SEQ ID No. 53 on the target of SEQ ID No. 142. These probes can be used in conjugation with probe of SEQ ID NO. 53, therefore, Jannes et al. teaches that probes can be used in a set in which the probes are 25 mer or less.

Though, Jannes et al. does not specifically teach the probe set of SEQ ID No. 17 and 19, he does suggest the fragmentation of a larger fragment into smaller oligonucleotide probes for the detection of staphylococcus species.

Therefore, the ordinary artisan would have been motivated to select any number of oligonucleotide fragments from the 16S-23S spacer region including SEQ ID Nos 17 and 19, which are fragments of SEQ ID No. 142. The art of designing probes (oligonucleotides) at the time the invention was made was very well described in the art. The art uses alignment programs to align sequences of interest and then uses algorithms to select and test probes and primers for their desired function of either detecting or distinguishing particular organisms. Designing probes that are equivalents to those taught in the art is routine experimentation. The prior art teaches the parameters and objectives involved in the selection of oligonucleotides that function as probes, see Jannes et al. Moreover there are many Internet web sites that provide free downloadable software to aid in the selection of probes drawn from genetic data recorded in a spreadsheet. The prior art is replete with guidance and information necessary to permit the ordinary artisan in the field of nucleic acid detection to design probes. The claimed probes are prima facie obvious over the cited references in the absence of secondary considerations, given the extensive teachings in the art. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to use the amplified sequence of Jannes et al. and design constraints of probes taught by Jannes et al. to obtain equivalent alternative probes of the claimed invention. The ordinary artisan would be motivated to have designed and test new probes to obtain additional oligonucleotides that function to detect *Staphylococcus* and identify oligonucleotides with improved properties.

Art Unit: 1634

**Conclusion**

10. No Claims are allowed

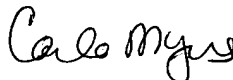
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Katherine Salmon  
Examiner  
Art Unit 1634



CARLA J. MYERS  
PRIMARY EXAMINER